

REMARKS

Claims 1, 4-10, and 12-75 are currently pending. Claims 14-17 and 20-75 are withdrawn. Claims 2-3 and 11 are cancelled. Claims 1, 4-10, 12-13, and 18-19 stand rejected.

Rejections under 35 U.S.C. §112

Claims 7 and 18 are rejected under 35 U.S.C. §112, second paragraph for insufficient antecedent basis. Specifically, in claim 7, the objected term is 'particulate' and in claim 18, the objected phrase is 'wherein LHRH is conjugated to a T helper cell epitope'. Applicants have amended the claims to replace 'particulate' with "microparticulate" in claim 7 and to delete the phrase 'wherein LHRH is' in claim 18 in order to address the Examiner's concerns. Reconsideration and withdrawal of the §112 rejections to claims 7 and 18 are respectfully requested.

Rejections under 35 U.S.C. §103

Claims 1, 5, 7-10, 12-13, and 18-19 are rejected under 35 U.S.C. §103(a) as being unpatentable over Krieg, et al. (WO 01/22972) in view of Ladd, et al. (WO 94/25060) as evidenced by result no. 1 of the rag search summary page. The Examiner admits that Krieg is not an anticipatory publication, however now contends that Krieg, et al. suggests the claimed composition in view of Ladd. Applicants respectfully disagree with the Examiner's contention.

As previously presented, Krieg reports that pyrimidine rich (Py-rich) or TG nucleotides do not require CpG oligonucleotides and the surprising finding that nucleic acid sequences which do not contain CpG motifs are immunostimulatory themselves. Krieg also reports that pyrimidine rich (Py-rich) or TG nucleotides alone are sufficient to provoke an immune response. See, Page 2, lines 17-32 and Page 16, lines 23-32 of Krieg, et al. In fact, Krieg teaches away from adding additional immunogens in view of the effectiveness of the nucleotides alone for evoking an immune response.

The Examiner admits that Krieg, et al. does not teach the cationic peptide immunogen that comprises a target B cell antigen or a CTL epitope and a T helper cell epitope as antigen. However, it is the Examiner's contention that Krieg, in combination with Ladd, et al. which teaches a cationic peptide immunogen capable of provoking an immune response, makes obvious the claimed invention.

Ladd, et al. report synthetic peptides capable of inducing antibodies against LHRH. In one embodiment, T helper cell epitopes are added to evoke an antibody response. However, regardless of whether the cationic peptide of SEQ ID NO:9 as indicated in the instant application and claims (Claims 19 and 20) is disclosed in Ladd, Krieg teaches away from using a target B cell or CTL epitope and T helper cell epitope.

Moreover, as pointed out previously, the claimed invention is directed to a microparticulate complex, a chemical entity formed between the cationic immunogenic peptide and the anionic CpG oligonucleotide. Specific conditions are used to form the complex. See, page 43 [0128] to [0131], and page 45, Example 1 and Table 3 of the specification. Contrary to the Examiner's contention, there is no ergo formation of the complex merely with co-administration of a CpG oligonucleotide and leuprolide acetate. Neither Krieg et al. nor Ladd et al. disclose, teach, or suggest the formation of a complex. In fact, there is no motivation to form a complex. There is no motivation to use the Ladd et al peptide immunogen to form a complex with the CpG oligonucleotide of Krieg, et al when there is no teaching and no suggestion in Krieg to add an immunogen to form of a complex.

As the Examiner is aware, a finding of obviousness cannot be based on hindsight based on the Applicants' disclosure and applied to the prior art. Obviousness may only be found based on what is taught and suggested in the prior art itself. For this reason, claims 1, 5, 7-10, 12-13, and 18-19 are not obvious in view of the combination of Krieg, et al. and Ladd, et al. Accordingly, applicants respectfully request reconsideration and withdrawal of the §103 rejection to these claims.

Claims 4 and 6 are further rejected under 35 U.S.C. §103(a) as being unpatentable over Krieg, et al. in view of Ladd, et al. as applied to claim 1. Applicants respectfully traverse this rejection.

Regardless of whether the cationic peptide immunogen is a mixture of synthetic peptide immunogens as disclosed in instant dependent claims 4 and 6, the independent claim 1 of a microparticulate complex comprising a cationic peptide immunogen of a target B cell antigen or a CTL epitope and a T helper cell epitope and anionic CpG oligonucleotide having specific parameters is not taught or suggested. Reconsideration and withdrawal of this §103 rejection to claims 4 and 6 are respectfully requested.

Dependent Claims

Applicants have not independently addressed all of the rejections of the dependent claims. Applicants submit that for at least similar reasons as to why independent claim 1 from which all of the dependent claims depend is believed allowable as discussed *supra*, the dependent claims are also allowable. Applicants however, reserve the right to address any individual rejections of the dependent claims and present independent bases for allowance for the dependent claims should such be necessary or appropriate.

Double Patenting

Claims 1-3, 5, 7-13 and 18-19 are provisionally rejected under 35 U.S.C. §101 as claiming the same invention as that of claims 1-11 and 16-17 of copending application no. 10/355,161 (U.S. Publication No. 2004/0009897). Since the conflicting claims have not in fact been patented, this is a provisional statutory type double patenting rejection.

In response, applicants respectfully request that the provisional statutory double-patenting rejection and rejection under 35 U.S.C. §101 be held in abeyance due to the provisional nature of the rejection until one of the applications is

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allowed. Upon notice of otherwise allowable subject matter, applicants will address the rejection. Applicants note that it is proper when dealing with otherwise allowable subject matter in co-pending applications to withdraw a provisional rejection in the most advanced application, allow it to issue, and make a (non-provisional) rejection in the remaining applications.


CONCLUSION

It is believed that the claims 1, 4-10, 12-13, and 18-19 as presented herein are allowable. Thus, applicants respectfully submit that the invention as recited in the claims as presented herein is allowable over the art of record, and respectfully request that the respective rejections and objections be withdrawn.

AUTHORIZATION

Applicants believe that no additional fees are necessary, however, should any such fees be due, the Commissioner is hereby authorized to charge any additional fees which may be required for this Amendment, or credit any overpayment, to Deposit Account No. 13-4500, Order No. 1151-4172. A
DUPLICATE COPY OF THIS SHEET IS ATTACHED.

Respectfully submitted,


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